APR 1 2 2013

PREMARKET NOTIFICATION
510(K)
SAFETY AND EFFECTIVENESS SUMMARY
(as required by 21 CFR § 807.92)

A. 510(k)Number:
K113439

B. Purpose for Submission:
New device

C. Measurand:
Autoantibodies against AMA-M2, M2-3E (BPO), Sp100, PML, gp210, LKM-1, LC-1 and SLA/LP

D. Type of Test:
Qualitative immunoblot (solid phase ELISA)

E. Applicant:
EUROIMMUN US INC.

F. Proprietary and Established Names:
EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG)

G. Regulatory Information:

1. Regulation:
   21 CFR §866.5090 - Antimitochondrial antibody immunological test system
   21 CFR §866.5660 - Multiple autoantibodies immunological test system.
2. Classification:
   Class II
3. Product code:

NBS	Multiple autoantibodies immunological test system.	LKM-1:
Subsequent Product Codes:		
DBM	Antimitochondrial antibody immunological test system.	(AMA-M2/M2-3E (BPO))
NIY	Multiple autoantibodies immunological test system.	(SLA/LP)
NUM	Antimitochondrial antibody immunological test system.	(Sp100)
NRI	Antimitochondrial antibody immunological test system.	(gp210)
	-	(PML)
	-	(LC-1)

4. Panel:
   Immunology

H. Intended Use:

1. Intended use(s):
   The EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) kit is an immune lineblot strip test intended for the qualitative detection of IgG class antibodies against 8 different antigens: AMA-M2, M2-3E (BPO), Sp100, PML, gp210, LKM-1, LC-1 and SLA/LP in human serum and plasma (EDTA, Li-heparin, Citrate). Detection of these antibodies is used as an aid in the diagnosis of autoimmune liver diseases in conjunction with other laboratory and clinical findings.

2. Indication(s) for use:
   Same as intended use.
3. Special conditions for the use statement(s):
   The EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) test kit is intended to be used in a clinical, reference or hospital laboratory. This kit is not designed for point-of-care testing. For prescription use only.
4. Special instrument requirements:
   Not applicable.

I. Device Description:

The EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) consists of antigen coated test strips, a positive control, alkaline phosphatase-labelled anti-human IgG conjugate, sample buffer, wash buffer concentrate, NBT/BCIP substrate solution, incubation tray, test instruction, evaluation protocol and reaction control card.

J. Substantial Equivalence Information:

1. Predicate device name (s):
   Inova Quanta Lite ELISAs (see table below).
2. Predicate 510(k) number(s):

EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) Antigens	Predicate device	510(k) number
M2 / M2-3E (BPO)	Quanta Lite M2 EP (MIT3) ELISA	K052262
Sp100	Quanta Lite Sp100 ELISA	K050662
PML	Quanta Lite Sp100 ELISA*	K050662
gp210	Quanta Lite gp210 ELISA	K040885
LKM-1	Quanta Lite LKM-1 ELISA	K000535
LC-1	Quanta Lite LKM-1 ELISA*	K000535
SLA/LP	Quanta Lite SLA ELISA	K021482

* As no FDA cleared test systems were available for two of the 8 antigens the Inova Sp100 ELISA was used as the predicate device for PML and the Inova LKM-1 ELISA as the predicate device for LC-1. D. A description of the relationship of these antigens is included in Bogdanos et al., World J Gastroenterol, 2008, 14(21), 3374-3387..

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
Intended Use	Qualitative detection of IgG class antibodies against 8 different antigens: AMA-M2, M2-3E (BPO), Sp100, PML, gp210, LKM-1, LC-1 and SLA/LP in human serum and plasma (EDTA, Li-heparin, Citrate).	Same (when combined)
Reaction principle	Enzyme immunoassay: enzyme labeled bound patient antibodies are detected with a chromogenic substrate that is converted to a visible colored product at the reaction site.	Same

Differences		
Item	Device	Predicate
Assay format	Qualitative	Semi-quantitative
Technology/ Procedure	Standard ELISA technique (solid phase ELISA): serum incubation with antigen coated strips, followed by a wash step, incubation with an anti-human IgG enzyme conjugate; wash step, incubation with substrate, wash step, air drying and evaluation.	Standard ELISA technique (solid phase ELISA): serum incubation with antigen coated wells, followed by a wash step, incubation with an anti-human IgG enzyme conjugate; wash step, incubation with substrate, stopping of the reaction with stop solution, photometric reading.

Differences			
Item	Device		Predicate
Antigens	AMA-M2	Natively purified from bovine heart, containing the 74 kDa E2 subunit of the pyruvate dehydrogenase complex (PDH) as the main component.	Affinity purified recombinant M2 EP MIT3.
	M2-3E (BPO)	Recombinant fusion protein, produced in E. coli, comprising the immunogenic domains of the E2 subunits of the branched-chain 2-oxoacid dehydrogenase (BCOADH), pyruvate dehydrogenase (PDH) and 2-oxoglutarate dehydrogenase (OGDH), together called M2-3E (synonyme: BPO).	
	Sp100	Recombinant Sp100, expressed by cloning the corresponding human cDNA in E. coli.	Purified Sp100 peptide.
	PML	Recombinant PML, expressed by cloning the corresponding human cDNA in E. coli.	
	gp210	Recombinant gp210, expressed by cloning the corresponding human cDNA in E. coli.	Purified gp210 peptide.
	LKM-1	Recombinant cytochrome P450 IID6, expressed by cloning the corresponding human cDNA in insect cells using a baculovirus vector.	Recombinant human cytochrome P450 IID6 antigen.
	LC-1	Recombinant LC-1 (formiminotransferase cyclodeaminase), expressed by cloning the corresponding human cDNA in insect cells using a baculovirus vector.	
	SLA/LP	Recombinant SLA/LP (a UGA suppressor tRNA-associated protein), expressed by cloning the corresponding human cDNA in E. coli.	Recombinant SLA antigen.
Samples	Serum or plasma (EDTA, Li-heparin, Citrate) 1:101 dilution		Serum 1:101 dilution
Controls	Positive control		3 controls (high positive, low positive, negative)
Conjugate	Alkaline phosphatase-labeled anti-human IgG (goat)		Goat anti-human IgG labeled with horseradish peroxidase
Substrate	BCIP/NBT		TMB
Reported results	positive/negative (qualitative)		Units (qualitative)

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle:

The EUROLINE uses different purified antigens that have been coated and applied in easy to read lines onto a membrane. Antibodies are detected via a secondary antibody linked to an enzyme. The principle of the EUROLINE is that of an enzyme linked immunosorbent assay (ELISA), using a membrane as the solid phase instead of microtiter wells.

Patient samples are diluted 1:101 in sample buffer, 1.5 ml of diluted patient sample are added to the test strip lying in the incubation channel and incubated for 30 minutes at room temperature. After incubation the test strips are washed with diluted wash buffer to remove unbound antibodies and 1.5 ml of the diluted anti-human IgG enzyme conjugate reagent is added to each channel. After an additional 30-minutes incubation at room temperature, the test strips are again washed with wash buffer to remove any unbound enzyme conjugate and 1.5 ml of the substrate solution is added. The strips are incubated for 10 minutes at room temperature and then aspirated and washed with dist. water. The test strips can be evaluated visually by comparison of the band intensity with the reaction control card.

The control band on the strips contains (non-specific) anti-human IgG, which reacts with the sample IgG to show a strong color reaction if the incubation was performed correctly and so represents a function test on each single strip. If the control band is negative, the test is invalid and should be repeated.

The positive control contains a mixture of the targeted antibodies which bind to the antigen coated on the blot strips. A strip incubated with the positive control shows a positive result. If the positive control is negative, the test results are invalid and should be repeated.

The qualitative results are reported for each individual antibody separately. The interpretation of the test results does not include a combined score or diagnosis.
Note: The EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) does not contain all antigens necessary for a complete diagnosis of autoimmune liver diseases. Especially in autoimmune hepatitis type 1, antibodies against smooth muscle and nuclear antigens are relevant. Testing for the presence of these antibodies should be investigated by the laboratory in addition to the antigens contained in this test. In the studies contained in this submission, only the antigen spectrum of the EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) was investigated.

M. Performance Characteristics (where applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Reproducibility was investigated by repeated determinations of different samples covering the whole range of antigens of the EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG). The samples were tested for intra-assay reproducibility in 20 replicates on one day using the same kit lot. Inter-assay reproducibility was investigated in 20 different runs, each run performed by the same technician with a single determination on a different day using the same kit lot. Inter-lot reproducibility was tested in 3 different runs using 3 different kit lots, each run performed with a single determination. Reproducibility was found to be sufficient as no positive sample was found negative and vice versa.
   To investigate the influence of different individuals reading the intensity of the bands, different samples covering the whole range of antigens were evaluated by three different technicians and under 3 different light conditions (sunlight, Neon light and electric bulb light), each run performed with a single determination. No deviation was observed between the individual readings and from the light conditions.

   b. *Linearity/assay reportable range:*

   Not applicable.

   c. *Traceability, Stability, Expected values (controls, calibrators or methods):*

   A recognized standard or reference material for antibodies against AMA-M2, M2-3E, Sp100, PML, gp210, LKM-1, LC-1 and SLA/LP is not available.

   d. *Detection limit:*

   Not applicable.

   e. *Analytical specificity:*

   Cross-reactivity: The quality of the antigen substrates and the antigen source assure a high level of specificity for the EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG). The test system allows specific detection of IgG class antibodies against AMA-M2, M2-3E, sp100, PML, gp210, LKM-1, LC-1 and SLA/LP. Cross reactivity was investigated using serologically characterized panels from the following groups: Autoantibodies against granulocyte cytoplasm (ANCA; n = 10), autoantibodies against thyroid gland antigens (n = 10) and autoantibodies against islet cell antigens (ICA; n = 10), autoantibodies against cardiolipin/anti-phospholipid syndrome (APS; n = 5) and the CDC ANA reference panel (n = 12) as well as clinical panels from the following groups: Autoimmune hepatitis type 1 (AIH-1; n = 84), primary sclerosing cholangitis (PSC; n = 19), systemic lupus erythematosus (SLE; n = 10), rheumatoid arthritis (RA; n = 50), celiac disease (n = 7), non-alcoholic steatohepatitis (n = 30) and viral hepatitis (HBV, HCV; n = 39). Only 9 samples of these 286 total samples were found positive with the EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) for a few antigens only.

   3 AIH tested positive for SLA/LP these three samples should not be considered cross-reactive as SLA/LP is associated with AIH-1.
   Interference: Different samples were spiked with potential interfering substances in 3 different concentrations. No interference was observed with haemolytic, lipaemic or icteric samples for concentrations of up to 500 mg/dl for haemoglobin, 2000 mg/dl for triglycerides and 40 mg/dl for bilirubin.

   f. *Assay cut-off:*

   The cut-off intensity is defined as the lowest limit of a clearly visible band.

2. Comparison studies:

a. Method comparison with predicate device:

A clinical study was performed with 295 clinically characterized samples (99 from patients with autoimmune hepatitis (AIH), 104 from patients with primary biliary cirrhosis as well as 42 from patients with viral hepatitis and 50 from patients with rheumatoid arthritis (RA) obtained from different sources. AIH cases were defined on the criteria of the International Autoimmune Hepatitis Group (IAIHG) and the recent recommendations for AIH issued by the American Association for the Study of the Liver Diseases (AASLD). PBC cases were defined on the basis of the consensus statements of both, the American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL): the presence of disease-related autoantibodies, more specifically AMA, is one of three criteria required for a definite diagnosis of PBC.

The samples were tested with the EUROIMMUN EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) and with the Inova ELISA kits as the predicate devices. To investigate the range close to the cut-off , 6 to 29 artificial samples for each antigen were created by mixing positive samples with negative samples of the same matrix as diluent– these samples were tested with the relevant reference ELISAs only, resulting in different total numbers. The results of the study are shown in the table below. Borderline results (Inova) were not included in the agreement calculations. 95% C.I.'s were calculated by the exact method.

The EUROLINE was slightly more sensitive for the detection of gp210 than the predicate assay assay. The predicate assay uses a synthetic peptide corresponding to a 25 amino acid stretch in the C-terminal cytosolic domain of gp210. In contrast, the EUROLINE utilizes a recombinant polypeptide corresponding to the 15 kDa C-terminal portion of the perinuclear domain fused to the whole cytosolic domain of gp210. The "discrepant" samples in the comparison study are mainly from PBC patients.

			Inova Quanta Lite ELISA			Positive agreement Negative agreement	Discrepant samples	
			positive	borderline	negative	% (95% C.I.)	positive	negative
EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG)	n = 281		M2 EP (MIT3)			95.1% (88.9 – 98.4%) 98.9% (95.9 – 99.9%)	2 PBC	3 controls, 2 AIH
	AMA-M2 and/or M2-3E	positive	97	0	2			
		negative	5	4	173			
	n = 293		Sp100			94.4% (81.3 – 99.3%) 99.2% (97.2 – 99.9%)	1 PBC, 1 artificial	2 artificial
	Sp100	positive	34	1	2			
		negative	2	2	252			
	n = 296		gp210			100.0% (89.4 – 100.0%) 88.5% (84.0 – 92.1%)	16 PBC, 7 AIH, 6 AIH/PBC, 1 RA	none
	gp210	positive	33	2	30			
		negative	0	0	231			
	n = 325		LKM-1			92.6% (82.1 – 97.9%) 98.9% (96.8 – 99.8%)	3 AIH, 1 artificial	3 artificial
	LKM-1	positive	50	0	3			
		negative	4	1	267			
	n = 298		SLA			100.0% (88.4 – 100.0%) 99.6% (97.9 – 100.0%)	1 artificial	none
	SLA/LP	positive	30	0	1			
		negative	0	1	266			

b. Matrix comparison:

The use of EDTA, heparin (Li) and citrate plasma samples was confirmed for each antigen band by a correlation of 8 to 11 sample pairs of serum and corresponding plasma. The sample pairs were selected to cover the complete range of results (negative, positive and close to cut-off). The results of the plasma samples and the corresponding serum sample were compared and found to be sufficient as no positive sample was found negative and vice versa.

3. Clinical studies:

a. Sensitivity and specificity:

The EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) was validated using several panels with a total of 734 samples, obtained from different sites. The results of these studies are summarized below.

Sensitivity for Primary biliary liver cirrhosis (PBC)

Panel	n (men, women)	Mean age (age range)	EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) positive (% positive) (95% C.I.)				
			AMA-M2	M2-3E	Sp100	PML	gp210
Primary biliary liver cirrhosis	205 (20, 185)	58 y (22-90 y)	175 (85.4%) (79.8 – 89.9%)	160 (78.0%) (71.8 – 83.5%)	54 (26.3%) (20.5 – 32.9%)	58 (28.3%) (22.2 – 35.0%)	68 (33.2%) (26.8 – 40.1%)

Specificity for Primary biliary liver cirrhosis (PBC)

Panel	n (men, women)	Mean age (age range)	EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) negative (% negative) (95% C.I.)				
			AMA-M2	M2-3E	Sp100	PML	gp210
Autoimmune hepatitis	163 (20, 59, 84 unkn.)	38 y (1-86 y, 84 unkn.)	162 (99.4%)	162 (99.4%)	162 (99.4%)	163 (100.0%)	154 (94.5%)
Viral hepatitis	39 (16, 23)	48 y (25-84 y)	39 (100.0%)	39 (100.0%)	39 (100.0%)	39 (100.0%)	39 (100.0%)
Primary sclerosing cholangitis	19 (12, 7)	48 y (21-73 y)	19 (100.0%)	19 (100.0%)	19 (100.0%)	19 (100.0%)	19 (100.0%)
Further controls*	308 (140, 167, 1 unkn.)	18 y (0-83 y)	304 (98.7%)	307 (99.7%)	308 (100.0%)	304 (98.7%)	302 (98.1%)
Total	529		524 (99.1%) (97.8 – 99.7%)	527 (99.6%) (98.6 – 100.0%)	528 (99.8%) (99.0 – 100.0%)	525 (99.2%) (98.1 – 99.8%)	514 (97.2%) (95.4 – 98.4%)

Sensitivity for Autoimmune hepatitis (AIH)

Panel	n (men, women)	Mean age (age range)	EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) positive (% positive) (95% C.I.)		
			LKM-1	LC-1	SLA/LP
Autoimmune hepatitis	163 (20, 59, 84 unkn.)	38 y (1-86 y, 84 unkn.)	20 (12.3%) (7.7 – 18.3%)	15 (9.2%) (5.2 – 14.7%)	15 (9.2%) (5.2 – 14.7%)
Type 1	142 (16, 42, 84 unkn.)	48 y (20-86 y 84 unkn.)	2 (1.4%) (0.2 – 5.0%)	1 (0.7%) (0.0 – 3.9%)	15 (10.6%) (6.0 – 16.8%)
Type 2	21 (4, 17)	12 y (1-45 y)	18 (85.7%) (63.7 – 97.0%)	14 (66.7%) (43.0 – 85.4%)	0 (0.0%) (0.0 – 16.1%)

Specificity for Autoimmune hepatitis (AIH)

Panel	n (men, women)	Mean age (age range)	EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) negative (% negative) (95% C.I.)		
			LKM-1	LC-1	SLA/LP
Primary biliary liver cirrhosis	205 (20, 185)	58 y (22-90 y)	204 (99.5%)	205 (100.0%)	199 (97.1%)
Viral hepatitis	39 (16, 23)	48 y (25-84 y)	39 (100.0%)	39 (100.0%)	39 (100.0%)
Primary sclerosing cholangitis	19 (12, 7)	48 y (21-73 y)	19 (100.0%)	19 (100.0%)	19 (100.0%)
Further controls*	308 (140, 167, 1 unkn.)	18 y (0-83 y)	308 (100.0%)	306 (99.4%)	307 (99.7%)
Total	571		570 (99.8%) (99.0 – 100.0%)	569 (99.6%) (98.7 – 100.0%)	564 (98.8%) (97.5 – 99.5%)

*from the following groups: systemic lupus erythematosus (n = 10), Sjögren's syndrome (n = 5), systemic sclerosis (n = 5), myositis (n = 4), rheumatoid arthritis (n = 50), diabetes (n = 9), celiac disease (n = 7), A1 antitrypsin deficiency (n = 30), Alagille syndrome (n = 29), biliary atresia (n = 35), giant cell hepatitis (n = 16), non-alcoholic steatohepatitis (n = 30), haemochromatosis (n = 17), progressive familial intrahepatic cholestatis (n = 31), Wilson's disease (n = 30)

b. Other clinical supportive data (when a. and b. are not applicable):
Not applicable.

4. Clinical cut-off:
See Assay cut-off.

5. Expected values/Reference range:
The levels of IgG antibodies against the antigens AMA-M2, M2-3E, Sp100, PML, gp210 LKM-1, LC-1 and SLA/LP, were analyzed in a panel of 150 healthy blood donors. None of these samples were found positive.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

04.09.2013 — *Date*

Michael Locke/Dir. Of Regulatory Affairs — *Name/Title*

Michael Locke — *Signature*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 12, 2013

EUROIMMUN US INC.
c/o Ms. Kathryn Kohl
Managing Director
1100 The American Road
Morris Plains, NJ 07950

Re: k113439
Trade/Device Name: EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) Kit
Regulation Numbers: 21CFR§866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Codes: DBM, NUM, NRI, NIY, NBS
Dated: April 10, 2013
Received: April 11, 2013

Dear Ms. Kohl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if Known): **k113439**

Device Name: EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) Kit

Indications for Use:

The EUROLINE Profile Autoimmune Liver Disease 8 Ag (IgG) Kit is an immune line-blot strip test intended for the qualitative detection of IgG class antibodies against 8 different antigens: AMA-M2, M2-3E (BPO), Sp100, PML, gp210, LKM-1, LC-1 and SLA/LP in human serum and plasma (EDTA, Li-heparin, Citrate). Detection of these antibodies is used as an aid in the diagnosis of autoimmune liver diseases in conjunction with other laboratory and clinical findings.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics
and Radiological Health

510(k) k113439